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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,680	10/17/2006	Yuki Takii	TIP-06-1314	2791
35811 7590 03/04/2010 IP GROUP OF DLA PIPER LLP (US) ONE LIBERTY PLACE 1650 MARKET ST, SUITE 4900 PHILADELPHIA, PA 19103				
			EXAMINER KILPATRICK, BRYAN T	
			ART UNIT 1797	PAPER NUMBER
			NOTIFICATION DATE 03/04/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto.phil@dlapiper.com

### Office Action Summary

**Application No.**

10/593,680

**Applicant(s)**

TAKII ET AL.

**Examiner**

BRYAN T. KILPATRICK

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. The claim amendments and remarks/arguments filed on 24 November 2009 have been entered and fully considered.
2. In light of Applicant's amendments, the objection to instant claim 1 has been withdrawn.
3. In light of Applicant's amendment, the rejection of instant claim 10 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph has been withdrawn.
4. Currently, instant claims 1-14 have been amended by Applicant's amendment and are pending.

***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,770,461 (Sakazume et al.), and further in view of U.S. Patent No. 4,815,978 (Mazza et al.).

In regards to instant claim 1, Sakazume et al. discloses a method and apparatus for separating magnetic particles that have immunocomplexes bound upon them, then

flocks of the bound magnetic particles are made using a magnetic field, which are then bound to the reaction container walls that the materials are located inside via a stronger magnetic field (Abstract). Furthermore, Sakazume et al. discloses a method where applying varying magnetic fields causes rotational motion (col. 3, lines 1-2) and shaking (col. 3, lines 16-20) of magnetic particles, and further employs an agitation device (col. 5, lines 16-34).

Sakazume et al. discloses the use of a nozzle for removing unnecessary liquids in the Abstract, but it does not expressly disclose the use of a mixing medium such as air. However, Mazza et al. recites in claims 1-31 and Figure 9 of an apparatus and method for mixing liquid samples in a cuvette using an air jet supplied through a nozzle. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nozzle of Sakazume et al. to supply an air jet for mixing, similarly to the method and apparatus taught by Mazza et al. The motivation would have been to be capable of thoroughly mixing the contents in a reaction container (Mazza et al. Abstract) in addition to being capable of removing liquid material when needed (Sakazume et al. Abstract).

In regards to instant claims 2-3, Sakazume et al. discloses magnetic particles for immobilization that can bind to the walls of a reaction container (Abstract).

In regards to instant claim 4, claim 4 of Sakazume et al. recites diameters for magnetic particles used for immobilizing immunocomplexes, which suggest circular particles.

In regards to instant claims 5 and 7, claim 4 of Sakazume et al. recites diameters for magnetic particles used for immobilizing immunocomplexes, which suggest circular particles. Sakazume et al. discloses a method and apparatus for separating magnetic particles that have immunocomplexes bound upon them, and then flocks of the bound magnetic particles are made using a magnetic field, which are then bound to the reaction container walls that the materials are located inside via a stronger magnetic field (Abstract). Mazza et al. recites in claims 1-31 and Figure 9 of an apparatus and method for mixing liquid samples in a cuvette using an air jet supplied through a nozzle.

In regards to instant claims 6, 8, and 11; Sakazume et al. discloses a method where applying varying magnetic fields causes rotational motion (col. 3, lines 1-2) and shaking (col. 3, lines 16-20) of magnetic particles, and further employs an agitation device (col. 5, lines 16-34) for mixing.

In regards to instant claim 9, Sakazume et al. discloses a method where applying varying magnetic fields causes rotational motion (col. 3, lines 1-2) and shaking (col. 3, lines 16-20) of magnetic particles, and further employs an agitation device (col. 5, lines 16-34) for agitating a reaction container. Claim 4 of Sakazume et al. recites diameters for magnetic particles used for immobilizing immunocomplexes, which suggest circular particles.

In regards to instant claims 10 and 12, claim 4 of Sakazume et al. recites diameters for magnetic particles used to be 1-2 micrometers or 10-50 micrometers.

In regards to instant 13, Sakazume et al. discloses the analysis of a biological sample in col. 3, line 64. It is well known in the art that nucleic acids are encompassed by biological samples.

In regards to instant claim 14, Sakazume et al. discloses the binding and analysis of samples in a solution (col. 3, line 63 – col. 4, line 11).

### ***Response to Arguments***

Applicant's arguments/remarks filed 24 November 2009 concerning the rejection under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

Applicant states in p. 4-5 of the remarks that the combination of Sakazume et al. and Mazza et al. fails to meet the limitations of the instant claims; specifically, Applicant states that the combination would result in a methodology wherein the air is allowed to interact with the selective binding substance. Sakazume et al. discloses magnetic particles that have immunocomplexes bound upon them, flocks of the bound magnetic particles are made using a magnetic field, and then the flocks are then bound to the reaction container walls via a stronger magnetic field (Abstract). Sakazume et al. goes on to disclose the use of a nozzle for removing unnecessary liquids in the Abstract, but it does not expressly disclose the use of a mixing medium such as air. Mazza et al. recites in claims 1-31 and Figure 9 of an apparatus and method for mixing liquid samples in a cuvette using an air jet supplied through a nozzle. As previously stated above, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to use the nozzle of Sakazume et al. to supply an air jet for mixing, similarly to the method and apparatus taught by the Abstract of Mazza et al. Furthermore, Mazza et al discloses in Fig. 9 an air jet that is fed into the top of a container and causes mixing of a solution in the container. Since the flocks of Sakazume et al. are bound to the reaction container walls via a stronger magnetic field, it is apparent that the mixing air jet of Mazza et al. would not interact with the bound flocks.

Applicant further states in p. 4-5 of the remarks that, "The air bubbles exist in a solution preliminarily before stirring and the air bubbles are not able to be supplied by an air jet under stirring in the Applicants' Claim 1." In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within



TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN T. KILPATRICK whose telephone number is (571)270-5553. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. T. K./  
Examiner, Art Unit 1797

/Samuel P Siefke/  
Primary Examiner, Art Unit 1797